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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2014-0314 and EPA-HQ-OPP-2014-0489; FRL-9941-87]

Triclopyr; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends the tolerances for residues of triclopyr in milk and livestock commodities which are identified and discussed later in this document, and amends the tolerance expressions to include triclopyr choline salt. Dow AgroSciences, LLC requested these tolerance changes under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective *[insert date of publication in the Federal Register]*.

Objections and requests for hearings must be received on or before *[insert date 60 days after date of publication in the Federal Register]*, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The dockets for this action, identified by docket identification (ID) numbers EPA-HQ-OPP-2014-0314 and EPA-HQ-OPP-2014-0489, are available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open

from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703)305-7090; email address: RDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl. To access the OCSPP test guidelines referenced in this document electronically, please go to <http://www.epa.gov/test-guidelines-pesticides-and-toxic-substances>.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify by docket ID numbers EPA-HQ-OPP-2014-0314 and EPA-HQ-OPP-2014-0489 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID numbers EPA-HQ-OPP-2014-0314 and EPA-HQ-OPP-2014-0489, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of Wednesday, November 25, 2015 (80 FR 73695) (FRL-9937-14), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a revised pesticide petition (PP 4F8249) by Dow AgroSciences, LLC, 9330 Zionsville Rd., Indianapolis, IN 46268-1054. The revised petition requested that 40 CFR part 180.417(a)(1) be amended by establishing a tolerance for residues of the herbicide triclopyr, [(3,5,6-trichloro-2-pyridinyl)oxy] acetic acid, in or on the raw agricultural commodity milk, fat at 0.7 parts per million (ppm); and increasing the tolerance in or on milk from 0.01 ppm to 0.6 ppm. The petition also requested that 40 CFR part 180.417(a)(2) be amended by establishing tolerances for residues of triclopyr, [(3,5,6-trichloro-2-pyridinyl)oxy] acetic acid and its metabolite 3,5,6-trichloro-2-pyridinol (TCP), calculated as the stoichiometric equivalent of triclopyr, in or on the raw agricultural commodities of cattle, goat, hog, horse, and sheep meat byproducts at 0.7 ppm; by increasing tolerances in cattle, goat, hog, horse, and sheep fat from 0.05 ppm to 0.09 ppm;

and increasing tolerances in cattle, goat, hog, horse, and sheep meat from 0.05 ppm to 0.08 ppm.

In the **Federal Register** of Friday, September 5, 2014 (79 FR 53009) (FRL-9914-98), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4F8279) by Dow AgroSciences, LLC, 9330 Zionsville Rd., Indianapolis, IN 46268-1054. The petition requested that 40 CFR part 180.417(a)(1) and 180.417(a)(2) be amended to include residues of the herbicide triclopyr choline salt as triclopyr, [(3,5,6-trichloro-2-pyridinyl)oxy] acetic acid, including its metabolites and degradates, in or on the raw agricultural commodities listed.

The documents referenced summaries of the petitions prepared by Dow AgroSciences, LLC, the registrant, which are available in the dockets at <http://www.regulations.gov>. The petition summary for PP 4F8249 is located in docket number EPA-HQ-OPP-2014-0314, and the petition summary for PP 4F8279 is located in docket number EPA-HQ-OPP-2014-0489. Several comments were received on the notices of filing. EPA's response to those comments are discussed in Unit IV.D.

Based upon review of the data supporting the petitions, EPA has (1) determined that a tolerance for milk fat is not required; (2) increased the proposed tolerances for the fat and meat of cattle, goat, hog, horse, and sheep; (3) decreased the proposed tolerances for the meat byproducts of cattle, goat, hog, horse, and sheep; and (4) determined that the current tolerances for kidney, liver, and meat byproducts except kidney and liver of cattle, goat, hog, horse, and sheep are not required.

EPA is also revising the tolerance expressions to correct the nomenclature of the chemical name, clarify the chemical moieties that are covered by the tolerances, and specify how compliance will be measured. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for triclopyr including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with triclopyr follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The bioequivalence of the three chemical forms of triclopyr (acid, triethylamine salt, and butoxyethyl ester) has been addressed through a variety of special studies with the salt and ester forms, including data on comparative disposition, plasma half-life, tissue distribution, and hydrolytic cleavage. Those studies were found to adequately address the issue of bioequivalence amongst these forms of triclopyr. Additionally, the currently available information supports the bioequivalence of triclopyr and triclopyr choline salt. Therefore, studies conducted with any one form of triclopyr have been used to support the toxicology database for triclopyr as a whole.

Triclopyr has been classified as having low acute toxicity via the oral, dermal, and inhalation routes. It is minimally-irritating (butoxyethyl ester) to corrosive (triethylamine salt) to the eye. It is a dermal sensitizer but not a dermal irritant.

Overall, effects in the triclopyr database were indicative of kidney and liver toxicity in rats and dogs, respectively. The primary effect observed in rats was degeneration of the proximal tubule of the kidney, which was seen at approximately the same dose in the subchronic oral and 2-generation reproduction toxicity studies. Body-weight decreases in rats were observed in the subchronic neurotoxicity and immunotoxicity studies at doses approximately ten times higher than doses resulting in kidney effects. In dogs, liver toxicity was evidenced by increased liver enzymes, increased liver weights, and liver histopathology at a similar dose as kidney effects in the rat. Changes in hematological parameters (decreased

packed-cell volume, decreased hemoglobin, and decreased red blood cell count) were also observed in dogs at the same dose.

There is evidence of increased qualitative susceptibility to offspring from triclopyr exposure in the rat 2-generation reproduction study, based on increased incidence of rare pup malformations observed in the presence of parental toxicity. There is also potential qualitative susceptibility in the rat developmental toxicity study; however, the evidence was not as conclusive as the reproduction toxicity study. Concern is low since effects are well-characterized with clearly established no-observed adverse-effect level/lowest-observed adverse-effect level (NOAEL/LOAEL) values, effects were seen in the presence of parental toxicity, and selected endpoints are protective of the observed effects.

Triclopyr has been classified as a “Group D Chemical - unable to be classified as to human carcinogenicity.” Although there was marginal evidence of carcinogenicity in animal studies (adrenal tumors in male rats and mammary gland tumors in female rats and mice), EPA has determined that the chronic reference dose (cRfD) will adequately account for all chronic effects, including carcinogenicity, likely to result from exposure to triclopyr. The Agency reached this conclusion employing a weight-of-evidence (WOE) approach after considering the following factors: (1) a lack of statistical significance at the high dose in pair-wise tests for all the tumors of concern; (2) for the adrenal tumors, there was a lack of dose-response and any pre-neoplastic lesions in the adrenal glands, along with evidence that the tumors were mainly benign; (3) for the mammary gland tumors, incidence in the concurrent control mice was at the low end of the historical control range; and (4) the chronic RfD is approximately 700-fold lower than the dose that induced the mammary gland tumors in female rats.

Acceptable subchronic neurotoxicity and immunotoxicity studies have been submitted and show no evidence of neurotoxicity or immunotoxicity.

Specific information on the studies received and the nature of the adverse effects caused by triclopyr as well as the NOAEL and the LOAEL from the toxicity studies can be found at <http://www.regulations.gov> in document, “Triclopyr. Human Health Risk Assessment for Petition to Amend Tolerance Expressions to Include Triclopyr Choline Salt; and Petition to Remove Grazing Restrictions for Dairy Cattle” on pp. 13-15 in docket ID numbers EPA-HQ-OPP-2014-0314 and EPA-HQ-OPP-2014-0489.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which the NOAEL and the LOAEL are identified. Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides>.

A summary of the toxicological endpoints for triclopyr used for human health risk assessment is shown in Table 1 of this unit.

Table 1.--Summary of Toxicological Doses and Endpoints for Triclopyr for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (Females 13-49 years of age)	NOAEL = 5 mg/kg/day $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x	Acute RfD = 0.05 mg/kg/day aPAD = 0.05 mg/kg/day	<u>2-Generation Rat</u> <u>Reproduction Study with</u> <u>Triclopyr Acid</u> LOAEL = 25 mg/kg/day based on increased incidence of rare malformations (exencephaly and ablepharia)
Acute dietary (General population including infants and	NOAEL = 100 mg/kg/day $UF_A = 10x$	Acute RfD = 1.0 mg/kg/day	<u>Developmental Rat</u> <u>Toxicity Study with</u> <u>Triclopyr BEE</u>

children)	$UF_H = 10x$ FQPA SF = 1x	aPAD = 1.0 mg/kg/day	LOAEL = 300 mg/kg/day based on maternal mortality. Additional effects seen at this dose included clinical signs, necropsy findings, decreased food and water consumption, and increased kidney and liver weights
Chronic dietary (All populations)	NOAEL= 5 mg/kg/day $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x	Chronic RfD = 0.05 mg/kg/day cPAD = 0.05 mg/kg/day	<u>2-Generation Rat Reproduction Study with Triclopyr Acid</u> LOAEL = 25 mg/kg/day based on degeneration of the proximal renal tubules
Incidental oral short-term (1 to 30 days) and intermediate-	NOAEL= 5 mg/kg/day UF_A = 10x $UF_H = 10x$	LOC for MOE = 100	<u>Subchronic Oral Rat Toxicity Study with Triclopyr Acid</u>

term (1 to 6 months)	FQPA SF = 1x		LOAEL = 20 mg/kg/day based on degeneration of the proximal renal tubules
Inhalation short-term (1 to 30 days) and intermediate-term (1 to 6 months)	Inhalation (or oral) study NOAEL= 5 mg/kg/day (inhalation absorption rate = 100%) UF _A = 10x UF _H = 10x FQPA SF/UF _{DB} = 10x	LOC for MOE = 1000	<u>Subchronic Oral Rat</u> <u>Toxicity Study with</u> <u>Triclopyr Acid</u> LOAEL = 20 mg/kg/day based on degeneration of the proximal renal tubules

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_{DB} = to account for the absence of data or other data deficiency. UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to triclopyr, EPA considered exposure under the petitioned-for tolerances as well as all existing triclopyr tolerances in 40 CFR 180.417. EPA assessed dietary exposures from triclopyr in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for triclopyr. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 2003-2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA assumed that triclopyr residues were present at tolerance levels in all commodities for which tolerances have been established or proposed, and that 100% of those crops were treated with triclopyr.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2003-2008 NHANES/WWEIA. As to residue levels in food, EPA assumed that triclopyr residues were present at tolerance levels in all commodities for which tolerances have been established or proposed except milk, and that 100% of those crops were treated with triclopyr. An average anticipated residue (AR) calculated from a livestock feeding study was used for all milk commodities.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has determined that the chronic RfD will adequately account for all chronic effects, including carcinogenicity, that are likely to result from triclopyr exposure. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use PCT information in the dietary assessment for triclopyr. However, EPA did use anticipated residue information for milk commodities in the chronic dietary assessment. Tolerance-level residues and 100 PCT were assumed for all other food commodities.

Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

2. *Dietary exposure from drinking water.* EPA calculated and required setback distances from the application site to the functional potable water intake in order to maintain average drinking water concentration levels below 400 parts per billion (ppb). Since potable water intakes are required to be turned off until triclopyr concentration levels are below 400 ppb, EPA has determined that for acute and chronic dietary risk assessments, the water concentration value of 400 ppb is appropriate to use to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Triclopyr is currently registered for the following uses that could result in residential exposures: Aquatic and turf areas. EPA assessed residential exposure using the following

assumptions: Handler inhalation exposure from spot applications to turf for adults, post-application inhalation and ingestion exposures of water from swimming for children 3 to <6 years old, and post-application incidental oral exposure to turf for children 1 to <2 years old. The dermal route of exposure is not quantitatively assessed because there is no dermal hazard. Short-term residential handler exposure, and short- and intermediate-term residential post-application exposures are expected. Chronic exposures are not expected. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide>.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to triclopyr and any other substances.

3,5,6-trichloro-2-pyridinol, commonly known as TCP, is a metabolite of triclopyr, chlorpyrifos, and chlorpyrifos-methyl. Risk assessment of TCP was conducted in 2002, and the previous conclusions that the acute and chronic dietary aggregate exposure estimates are below EPA's level of concern (LOC) are still valid since the tolerances changes will not have a noticeable effect on dietary exposures to TCP. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such

chemicals, see EPA's website at <http://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* As summarized in Unit III.A., there is evidence of increased qualitative susceptibility to offspring from triclopyr exposure in the 2-generation reproduction toxicity study and potential qualitative susceptibility in the rat developmental toxicity study. However, the concern is low since effects are well-characterized with clearly established NOAEL/LOAEL values, effects were seen in the presence of parental toxicity, and selected endpoints, which are protective of the effects in adult animals, are protective of the observed effects.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X, with the exception for inhalation exposures where the FQPA SF is retained at 10X. These decisions are based on the following findings:

i. The toxicity database for triclopyr is adequate for characterizing triclopyr toxicity and quantification of hazard exposures. For assessing risks associated with inhalation exposures, the FQPA SF is retained at 10X to incorporate the database uncertainty factor (UF_{DB}) to account for the lack of a subchronic inhalation toxicity study.

ii. There is no indication that triclopyr is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is evidence of increased qualitative susceptibility to offspring from triclopyr exposure. However, the concern is low since effects are well-characterized with clearly established NOAEL/LOAEL values, effects were seen in the presence of parental toxicity, and selected endpoints, which are protective of the effects in adult animals, are protective of the observed effects.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues for all crops except milk commodities and drinking water in which anticipated residues were used. EPA used conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by triclopyr.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by

comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to triclopyr will occupy 53% of the aPAD for females 13-49 years old, and 8% of the aPAD for all infants less than 1 year old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to triclopyr from food and water will utilize 46% of the cPAD for all infants less than 1 year old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3. regarding residential use patterns, chronic residential exposure to residues of triclopyr is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Triclopyr is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to triclopyr.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in an aggregate MOE of 120 for children 1 to <2 years old (dietary exposure with post-application incidental oral exposure from turf use). Because EPA's level of concern for triclopyr is a MOE of 100 or below, this MOE is not of concern.

For adults and children 3 to <6 years old, an aggregate risk index (ARI) is used since the POD for the oral and inhalation routes of exposure are the same, but the LOC values for oral (MOE<100) and inhalation (MOE<1000) exposures are different. The ARIs are 3.6 for children 3 to <6 years old (dietary exposure with post-application inhalation and ingestion from aquatic use), and 1.4 for adults (dietary exposure with handler inhalation exposure from turf use). Since EPA's level of concern is an ARI below 1, these ARIs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Although triclopyr is currently registered for uses that could result in intermediate-term residential exposure, EPA determined that a quantified intermediate-term aggregate assessment is unnecessary since the short- and intermediate-term PODs are the same and the short-term aggregate provides a worst-case estimate of residential exposure and is therefore protective of the longer-term exposures.

5. *Aggregate cancer risk for U.S. population.* As summarized in Unit III.A., EPA has determined that an aggregate exposure risk assessment for cancer risk is not required based on WOE conclusions on the marginal evidence of carcinogenicity in two adequate rodent carcinogenicity studies and the use of the chronic RfD which will adequately account for any potential carcinogenic effects.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to triclopyr residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodologies (Methods ACR 77.2 and ACR 77.4, using gas chromatography with electron-capture detection (GC/ECD); Method GRM 97.02 using gas chromatography with mass-spectrometry detection (GC/MS)) are available to enforce the tolerance expression. The Food and Drug Administration (FDA) PESTDATA database dated 1/94 (Pesticide Analytical Manual (PAM) Vol. I, Appendix I) indicates that triclopyr is completely recovered (>80%) using multi-residue method PAM Vol. I Section 402. Data pertaining to multi-residue methods testing of triclopyr and its metabolites through Protocols B, C, D, and E have been submitted and forwarded to FDA.

The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established any MRL for triclopyr.

C. Revisions to Petitioned-For Tolerances

Based on the available residue chemistry data, EPA has determined that a tolerance for milk fat is not required. Also, EPA is increasing the proposed tolerances for fat (0.09 ppm) and meat (0.08 ppm) of cattle, goat, hog, horse, and sheep to 0.10 ppm, and decreasing the proposed tolerances for meat byproducts of cattle, goat, hog, horse, and sheep from 0.7 ppm to 0.50 ppm in order to harmonize with established Canadian MRLs. The current tolerances for kidney (0.5 ppm), liver (0.5 ppm), and meat byproducts except kidney and liver (0.05 ppm) of cattle, goat, hog, horse, and sheep are being removed and replaced by establishing tolerances for meat byproducts of cattle, goat, hog, horse, and sheep at 0.50 ppm.

EPA is also revising the chemical name of triclopyr in the tolerance expressions to reflect the preferred Chemical Abstract Service (CAS) nomenclature. Lastly, in accordance with Agency guidance on tolerance expressions, the tolerance expressions for triclopyr are revised by clarifying that the tolerances cover “residues of the herbicide triclopyr, including its metabolites and degradates as well as how residues of triclopyr are to be measured.”

D. Response to Comments

Several comments were received in both dockets, EPA-HQ-OPP-2014-0314 and EPA-HQ-OPP-2014-0489, containing general comments disapproving of the use and EPA’s approval of pesticides, and two similar comments stating that triclopyr should be banned due to its toxic effects on aquatic animals and its soil half-life. EPA understands these commenters’ concerns and recognizes that some individuals believe that pesticides should be banned on agricultural crops. However, the existing legal framework provided by Section 408 of the FFDCA states that

tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. These comments appear to be directed at the underlying statute and not EPA's implementation of it; the commenters have made no contention that EPA has acted in violation of the statutory framework. In addition, some of the comments stated that triclopyr's negative effects are detrimental to human health. EPA has concluded that there is a reasonable certainty of no harm to humans after considering the toxicological studies and the exposure levels of humans to triclopyr.

V. Conclusion

Therefore, tolerances are established for residues of triclopyr, 2-[(3,5,6-trichloro-2-pyridinyl)oxy]acetic acid, in or on cattle, meat byproducts at 0.50 ppm; goat, meat byproducts at 0.50 ppm; hog, meat byproducts at 0.50 ppm; horse, meat byproducts at 0.50 ppm; sheep, meat byproducts at 0.50 ppm; amended for milk at 0.60 ppm; cattle, fat at 0.10 ppm; cattle, meat at 0.10 ppm; goat, fat at 0.10 ppm; goat, meat at 0.10 ppm; hog, fat at 0.10 ppm; hog, meat at 0.10 ppm; horse, fat at 0.10 ppm; horse, meat at 0.10 ppm; sheep, fat at 0.10 ppm; and sheep, meat at 0.10 ppm.

The following livestock tolerances for "kidney," "liver," and "meat byproducts, except kidney and liver" are removed since these commodities will be combined under the "meat byproducts" tolerances: Cattle, kidney at 0.5 ppm; cattle, liver at 0.5 ppm; cattle, meat byproducts, except kidney and liver at 0.05 ppm; goat, kidney at 0.5 ppm; goat, liver at 0.5 ppm; goat, meat byproducts, except kidney and liver at 0.05 ppm; hog, kidney at 0.5 ppm; hog, liver at 0.5 ppm; hog, meat byproducts, except kidney and liver at 0.05 ppm; horse, kidney at 0.5 ppm; horse, liver at 0.5 ppm; horse, meat byproducts, except kidney and liver at 0.05 ppm; sheep,

kidney at 0.5 ppm; sheep, liver at 0.5 ppm; and sheep, meat byproducts, except kidney and liver at 0.05 ppm.

VI. Statutory and Executive Order Reviews

This action amends and establishes tolerances under FFDCA section 408(d) in response to petitions submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct

effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 11, 2016.

Susan Lewis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.417, revise paragraph (a)(1) introductory text, the commodity “Milk,” in the table in paragraph (a)(1) and paragraph (a) (2) to read as follows:

§ 180.417 Triclopyr; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the herbicide triclopyr, including its metabolites and degradates, in or on the commodities in the table below resulting from the application of the butoxyethyl ester of triclopyr, triethylamine salt of triclopyr, or choline salt of triclopyr. Compliance with the tolerance levels specified below is to be determined by measuring only triclopyr, 2-[(3,5,6-trichloro-2-pyridinyl)oxy]acetic acid.

Commodity	Parts per million
* * *	* * * *
Milk	0.60
* * *	* * * *

(2) Tolerances are established for residues of the herbicide triclopyr, including its metabolites and degradates, in or on the commodities in the table below resulting from the application of the butoxyethyl ester of triclopyr, triethylamine salt of triclopyr, or choline salt of

triclopyr. Compliance with the tolerance levels specified below is to be determined by measuring the combined residues of triclopyr, 2-[(3,5,6-trichloro-2-pyridinyl)oxy]acetic acid, and its metabolite 3,5,6-trichloro-2-pyridinol (TCP), calculated as the stoichiometric equivalent of triclopyr.

Commodity	Parts per million
Cattle, fat	0.10
Cattle, meat	0.10
Cattle, meat byproducts	0.50
Goat, fat	0.10
Goat, meat	0.10
Goat, meat byproducts	0.50
Hog, fat	0.10
Hog, meat	0.10
Hog, meat byproducts	0.50
Horse, fat	0.10
Horse, meat	0.10
Horse, meat byproducts	0.50

Sheep, fat	0.10
Sheep, meat	0.10
Sheep, meat byproducts	0.50

* * * *

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